REMARKS

Claims 1-85 are pending in the present application. The examiner stated that pending claims 1-44 are drawn to 14 independent or distinct inventions as follows (Office Communication, p. 2):

Group I: claim(s) 1, 4, 5, 6, 7, 21-48 and 74, drawn to a composition comprising a polypeptide which comprises an amino acid sequence substantially identical to the sequence of SEQ ID NOs: 22-43, 59, or 73-84, or a fragment or variant thereof, in combination with a physiologically acceptable carrier and a recombinant polypeptide comprising an amino acid sequence substantially identical to the sequence of SEQ ID NOs: 22-43, 59, or 73-84.

Group II: claim(s) 2, 3, 6, 7, 21-48, 75-81 and 83-84, drawn to a composition comprising a nucleic acid molecule encoding a polypeptide which comprises an amino acid sequence substantially identical to the sequence of SEQ ID NOs: 22-43, 59, or 73-84, or a fragment or variant thereof, in combination with a physiologically acceptable carrier and an isolated nucleic acid molecule comprising a nucleotide sequence substantially identical to the sequence of SEQ ID NOs: 1-21 or 60-72 and a kit comprising a reagent for detecting an A/E pathogen in a sample and a package insert with instructions for detecting the A/E pathogen in the sample, wherein the reagent comprises a probe or primer probe or primer substantially identical to: a) a nucleotide sequence selected from the group consisting of one or more of SEQ ID NOs: 1-21 or 60-72 or a fragment or variant thereof, or b) a nucleotide sequence encoding a polypeptide substantially identical to one or more of SEQ ID NO: 22-43, 59, 73-84 or a fragment or variant thereof.

Group III: claim(s) 8-48, drawn to a bacterium, or a preparation thereof, wherein the bacterium comprises a mutation in the bacterial genome in a nucleotide sequence that is substantially identical to SEQ ID NOs: 1-21 or 60-72.

Group IV: claim(s) 49-51 and 71-73, drawn to a method of detecting the presence of an A/E pathogen in a sample, the method comprising: a) providing a sample; and b) detecting the presence of a nucleic acid molecule comprising a nucleotide sequence substantially identical to a sequence selected from one or more of the group consisting of SEQ ID NOs: 1-21 or 60-72 or a fragment or variant thereof, c) detecting the presence of a nucleic acid molecule encoding a polypeptide substantially identical to a sequence selected from one or more of the group consisting of SEQ ID NOs: 22-43, 59, 73-84 or a fragment or variant thereof.

Group V: claim(s) 49, 50, 52 and 71-73, drawn to a method of detecting the presence of an A/E pathogen in a sample, the method comprising: detecting the presence of a polypeptide comprising an amino acid sequence substantially identical to a sequence selected from one or more of the group consisting of SEQ ID NOs: 22-43, 59, 73-84 or a fragment or variant thereof.

Group VI: claim(s) 53-58 and 71-73, drawn to a method for eliciting an immune response against an A/E pathogen, or component thereof, in an animal comprising administering to the animal an effective amount of the composition of any one of claims 1-7 thereby eliciting an immune response in the animal.

Group VII: claim(s) 53-58 and 71-73, drawn to a method for eliciting an immune response against an A/E pathogen, or component thereof, in an animal comprising administering to the animal an effective amount of the composition of any one of claims 15-48, or comprising administering to the animal an effective amount of the bacterium of any one of claims 8-14, thereby eliciting an immune response in the animal.

Group VIII: claim(s) 59-61 and 71-73, drawn to a method of treating or preventing infection by an A/E pathogen, the method comprising: a) identifying an animal having, or at risk for, an A/E pathogen infection; and b) administering to the animal an effective amount of

a compound that attenuates the virulence of an A/E pathogen, wherein the compound inhibits the expression, secretion, or biological activity of a polypeptide comprising an amino acid sequence substantially identical to the sequence of any one of SEQ ID NOs: 22-43, 59, 73-84.

Group IX: claim(s) 62 and 71-73, drawn to a method of attenuating the virulence of an A/E pathogen, the method comprising mutating one or more of a gene selected from the group consisting of nleA, nleB, nleC, nleD, nleE, nleF, nleG, and nleR, or a homologue thereof in the A/E pathogen, or mutating one or more of a nucleotide sequence in the genome of the A/E pathogen, wherein the nucleotide sequence is selected from SEQ ID NOs: 1-21 or 60-72, thereby attenuating virulence.

Group X: claim(s) 63-66 and 71-73, drawn to a method of screening for a compound that attenuates the virulence of an A/E pathogen, the method comprising: a) providing a system comprising: (i) a nucleic acid molecule comprising a nucleotide sequence substantially identical to SEQ ID NOs: 1-21 or 60-72 or a fragment or variant thereof; or (ii) a nucleic acid molecule encoding a polypeptide comprising an amino acid sequence substantially identical to SEQ ID NOs: 22-43, 59, 73-84 or a fragment or variant thereof b) providing a test compound and c) determining whether the test compound modulates the expression, secretion, or biological activity of the polypeptide or the nucleic acid molecule, wherein a change in the expression, secretion, or biological activity of the polypeptide or the nucleic acid molecule indicates a compound that attenuates the virulence of an A/E pathogen.

Group XI: claim(s) 63-66 and 71-73, drawn to a method of screening for a compound that attenuates the virulence of an A/E pathogen, the method comprising: a) providing a system comprising: a polypeptide comprising an amino acid sequence substantially identical to SEQ ID NOs: 22-43, 59, 73-84 or a fragment or variant thereof; b) providing a test compound; and c) determining whether the test compound modulates the expression, secretion, or biological activity of the polypeptide or the nucleic acid molecule, wherein a

change in the expression, secretion, or biological activity of the polypeptide or the nucleic acid molecule indicates a compound that attenuates the virulence of an A/E pathogen.

Group XII: claim(s) 67-73, drawn to a method of producing a A/E pathogen polypeptide comprising: a) providing a recombinant cell comprising: (i) a nucleic acid molecule comprising a nucleotide sequence substantially identical to SEQ ID NOs: 1-21 or 60-72; or (ii) a nucleic acid molecule encoding a polypeptide comprising an amino acid sequence substantially identical to SEQ ID NOs: 22-43, 59, or 73-84; and b) growing the recombinant cell under conditions that permit expression of the polypeptide.

Group XIII: claim(s) 82, drawn to use of the composition of any one of claims 1-7 or 15-48, the bacterium of any one of claims 8-14, the polypeptide of claim 74, or the nucleic acid molecule of claim 75, for the preparation of a medicament for eliciting an immune response against an A/E pathogen, or component thereof, or for reducing shedding or colonization of an A/E pathogen in an animal, or for treating or preventing infection by an A/E pathogen.

Group XIV: claim(s) 83 and 85, drawn to a kit comprising a reagent for detecting an A/E pathogen in a sample and a package insert with instructions for detecting the A/E pathogen in the sample wherein the reagent comprises an antibody that specifically binds a sequence selected from the group consisting of one or more of SEQ ID NOs: 22-43, 59, 73-84 or a fragment or variant thereof.

The examiner requested applicants elect a single Group for examination. In response to the Office Communication, applicants elect to prosecute the subject matter of Group VI, claim(s) 53-58 and 71-73, drawn to a method for eliciting an immune response against an A/E pathogen, or component thereof, in an animal comprising administering to the animal an effective amount of the composition of any one of claims 1-7 thereby eliciting an immune response in the animal. This election is made without traverse.

The examiner noted that applicants should also elect a species of bacterial antigen from nleA, nleB, nleC, nleD, nleE, nleF, nleG, nleH or Z2075, Z2149, Z2150, Z2151, Z2337, Z2338, Z2560, Z2976, or L0043 and the variant(s) that read on the elected species (Office Communication, p. 5). Applicants further elect the species of NleA, as embodied in SEQ ID NOS: 1-3 and 22-24. This election is made without traverse.

Applicants respectfully request prompt examination on the merits. If the examiner believes that a personal communication will expedite prosecution of this application, the examiner is invited to telephone the undersigned at the number provided.

Applicants petition for a five (5) month extension of time in the amount of $1,175. The Commissioner is hereby authorized to charge Deposit Account 19-2555 for the extension of time fees as well as any additional fees that may be required to render the present submission timely.

Respectfully submitted,
B. BRETT FINLAY ET AL.

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